

AUG 22 1993

K 962114

510(k) Summary
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The Arthro-Surgimat is a high flow arthroscopic pump classified under 21 C.F.R. § 888.1100 intended to distend joint cavities during arthroscopic procedures. It has been designed to react very quickly to various influences, thereby maintaining constant intraarticular pressure.

The arthroscopic pump described in this notification is substantially equivalent in design and construction to the Linvatec Apex Universal Irrigation System, K933873, and the Smith & Nephew InteliJET Fluid Management System, K912453, and has similar indications for use to those devices. The principal differences lie in the following features:

- Pressure measurement through multiple sensors at the pump head. The Apex device provides for pressure measurement through a single membrane at the end of an additional tube. The specific pressure measurement systems of the Smith & Nephew device are not known.
- 3 optional preselectable pressure levels (to be programmed by end-user):

Knee arthroscopy:	0 - 1 mm Hg
Shoulder arthroscopy:	0 - 80 mm Hg
Small Joints:	0 - 60 mm Hg

** (Please refer to specific pressure levels described in manual)

The Apex device contains no preselectable pressure levels; the Smith & Nephew device contains 4 preselectable pressure levels.

- Max. flow rate of 1500 ml/min. This is the same as the Smith & Nephew device; Apex provides 2000 ml/min.
- Foot pedal for temporary increase of preselected flow level for rinsing of joint after/during shaver use. The predicate devices offer an optional foot pedal having features that are not currently known.

The utility and safety of arthroscopic techniques using modern electronic high flow pumps is discussed in the following references, including the benefits and risks of such procedures and the importance of effective, well maintained instrumentation:

- A Comprehensive discussion of the use of distention methods is presented in the book "Arthroscopie: Diagnostika und Therapie" (1) by Harald Hempfling, 1995, in which the development of arthroscopic procedures is reviewed, including objective comparisons of arthroscopy vs. traditional methods of treatment. This extensive analysis of the instrumentation in this field includes comments on the use of modern high flow pumps, the selection of the optimal distention medium and a summary of other instruments necessary for arthroscopic procedures. (pp. 13-41)

This work is of particular interest due to the extensive review of arthroscopic techniques specific to various joints. This includes, but is not limited to, the knee, shoulder, wrist and elbow.

- In perhaps the most comprehensive work on arthroscopy, "Operative Arthroscopy, Second Edition" (2), an in-depth review of the history, techniques and modern apparatus of arthroscopic procedures is provided. Of special interest is the chapter on advanced arthroscopic instrumentation (pp. 7-13), in which irrigation systems are also discussed in detail. Other references to irrigation systems appears at pp. 75 and 256.

REFERENCES

1. Hempfling, Harald, "Arthroscopie: Diagnostika and Therapie", Landsberg, Germany: Ecomed Verlagsgesellschaft AG & Co. KG, 1995, 375 pages.
2. McGinty, John B. "Operative Arthroscopy, Second Edition" Philadelphia: Lippincott-Raven Publishers, 1995, 1500 pages. See "Advanced Arthroscopic Instrumentation" on pages 7-13.

For W.O.M. GmbH:
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Regulatory Affairs
May 1996